UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BELLION SPIRITS, LLC,
2911 Hunter Mill Road,
Suite 303
Oakton, VA 22124; and

CHIGURUPATI TECHNOLOGIES PRIVATE LTD.,
Plot No. 512/m/1. Road No. 31 Jubilee Hills,
Hyderabad, 500033, Andhra Pradesh, India,

Plaintiffs,

vs.

UNITED STATES OF AMERICA
c/o United States Attorney,
Judiciary Building
555 Fourth Street, N.W.
Washington, D.C. 20530;

U.S. DEPARTMENT OF TREASURY,
1500 Pennsylvania Avenue, N.W.
Washington, D.C. 20220;

STEVEN MNUCHIN, in his official capacity as SECRETARY,
U.S. DEPARTMENT OF TREASURY,
1500 Pennsylvania Avenue, N.W.
Washington, D.C. 20220;

ALCOHOL AND TOBACCO TAX AND TRADE BUREAU,
1310 G Street, N.W.
Washington, D.C. 20005; and

JOHN J. MANFREDA, in his official capacity as ADMINISTRATOR,
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU,
1310 G Street, N.W.
Washington, D.C. 20005,

Defendants.

Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. Plaintiffs Bellion Spirits, LLC and Chigurupati Technologies Private Ltd. (collectively "Plaintiffs"), by counsel, hereby submit this Complaint against Defendants Steven Mnuchin, Secretary, United States Department of the Treasury (in his official capacity); the Unites States Department of the Treasury; John Manfreda, Administrator, Alcohol and Tobacco Tax and Trade Bureau (in his official capacity); the Alcohol and Tobacco Tax and Trade Bureau ("TTB"); and the United States of America. The Plaintiffs seek a Declaratory Judgment holding that TTB's ban of two health-related statements (Claims VII and VIII *infra*) concerning the DNA-protective effects of NTX®, a legal additive to alcohol,[1] violates the First Amendment to the Unites States Constitution. In addition, the Plaintiffs seek a Declaratory Judgment holding that TTB violated the Federal Alcohol Administration Act ("FAA Act" or "FAAA") by improperly enforcing regulations and policies of a sister agency, the Federal Food and Drug Administration ("FDA"), and deferring to FDA's standards for the evaluation of dietary supplement and drug claims on the issue of whether the Plaintiffs' claims for alcohol containing NTX® were substantiated. The Plaintiffs also seek a Declaratory Judgment holding that the TTB's lack of rules, guidance, and standards governing the approval of health claims for alcoholic beverages deprives Plaintiffs of adequate Due Process under the Fifth Amendment to the United States Constitution. Plaintiffs respectfully request that this Court permanently enjoin the TTB from acting to prevent Plaintiffs from using the proposed health-related statements (Claims VII and VIII *infra*) on labels, in labeling, and in advertising of alcoholic beverages, subject only to a short, succinct, and reasonable disclaimer to avoid potential misleadingness.

[1] NTX® is a proprietary blend of glycyrrhizic acid, d-mannitol, and potassium sorbate.

INTRODUCTION

2. This Complaint arises from TTB's suppression of two health-related statements for use on the label, in the labeling, and in the advertising of NTX® containing alcoholic beverages, including wines, malt beverages, and distilled spirits.

3. The banned health-related statements, which concern reduction in alcohol-induced DNA damage, are Claims VII and VIII below, respectively, i.e.: (1) "NTX® helps protect DNA from alcohol-induced damage" and (2) "NTX® reduces alcohol-induced DNA damage."

4. Both health-related statements are truthful, substantiated by credible scientific evidence (with no contrary evidence present in the publicly available peer-reviewed scientific literature). Demonstrably true, the statements are not inherently misleading, particularly when accompanied by a reasonable disclaimer to avoid potential misleadingness, such as the disclaimer Plaintiffs have proposed, or any other short, succinct, and reasonable disclaimer that may be proposed by TTB (and would be accepted by Plaintiffs). By censoring *in toto* the health-related statements in controversy, TTB violates the First Amendment and denies consumers access in the market, including at the point of sale, to factual information concerning the potential of NTX® to reduce the risk of alcohol-induced DNA damage. By censoring Plaintiffs' speech, TTB casts a pall of censorship over the alcohol market, keeping from it innovations designed to reduce the deleterious effects of alcohol on the body.

5. Additionally, in reliance on an FDA evaluation of the science under FDA's inapposite dietary supplement and drug claim standards, TTB categorically rejected original research of high methodological quality germane to the effects of NTX® on alcohol: state of the

art testing revealing that alcohol damages DNA and revealing the protective effects of NTX® on reducing that DNA damage. TTB categorically rejected peer-reviewed scientific articles that the scientific community accepts as persuasive, including, but not limited to, animal, *in vitro*, and clinical studies. Relying thus on FDA's standards for food and drug claims rather than its own germane to alcohol, TTB failed to review substantively the totality of the scientific evidence, and instead reviewed only a small fraction of it, which evaluation created the false impression that the scientific evidence in support of the two health-related statements was insufficient when in fact, it was credible and fully supportive. TTB's decision to exclude categorically scientific evidence supporting the health-related statements and thereby condemn the statements is an act of speech suppression that violates the First Amendment and is part of a long line of cases involving speech suppression by BATF, now TTB.

6. Professing a lack of expertise sufficient to review the science supplied to it in support of the health-related statements for alcoholic beverages, TTB impermissibly, beyond the limits of its own enabling statute, delegated its statutory duty to perform the review to FDA, which agency has no statutory authority to perform that review. TTB impermissibly relied upon FDA to determine whether the health-related statements for use on alcoholic beverages were truthful and adequately substantiated under FDA's standards which are germane not to alcohol but to dietary supplements and drugs. TTB then acted in excess of its grant of statutory authority under 27 U.S.C.A. § 202(f) when it accepted FDA's review based on standards inapplicable to alcoholic beverages as a substitute for decision under its own standards under 27 C.F.R. § 5.42 and under its own enabling Act, 27 U.S.C. § 205 *et seq*. Such ultra vires action by TTB and FDA violates the enabling acts of both agencies, 21 U.S.C. § 301, *et seq*., and 27 U.S.C. § 201, *et seq*.

7. Plaintiffs ask this Court to declare TTB's censorship of the two scientifically-backed NTX® health-related statements (Claims VII and VIII) unlawful under the First Amendment to the United States Constitution and under the TTB and FDA's enabling Acts. The Plaintiffs further ask this Court to enjoin TTB from taking any action that would prevent Plaintiffs from disseminating the NTX® health-related statements on labels, in labeling, and in advertising of their Bellion brand alcoholic beverages, including, but not limited to, Bellion Vodka, excepting allowance of a government mandated short, succinct, and reasonable disclaimer as necessary to avoid potential misleadingness, consistent with the First Amendment precedent of this Court limiting such disclaimers.

JURISDICTION AND VENUE

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question jurisdiction), and 28 U.S.C. § 1346 (jurisdiction where the United States is a defendant).

9. The challenged decision is a final agency action of TTB.

10. There is an actionable and justiciable controversy between Plaintiffs and Defendants requiring resolution by this Court.

11. This Court has personal jurisdiction over Defendants.

12. The Plaintiffs' requested relief is authorized under 28 U.S.C. § 2201 (declaratory relief) and 28 U.S.C. § 2202 (further relief), as well as 5 U.S.C. § 702.

13. Venue is properly vested in this Court under 28 U.S.C. § 1391(e) because the Defendants reside in this district and a substantial part of the events giving rise to this action occurred in this district.

PARTIES

14. ***Bellion Spirits, LLC***. Bellion Spirits, LLC ("Bellion Spirits") is regulated by the TTB as an independent distributor of its Bellion brand Vodka, and it has wholesaler and importer permits from TTB. Its contract bottler has two TTB-approved labels for Bellion brand Vodka that refer to NTX®.[2] Bellion Spirits was founded to pioneer innovation in the alcohol beverage industry, through the introduction of functional alcoholic beverages, which generally retain the customary characteristics of alcoholic beverages, while providing protection for the liver and for genes against alcohol's unwanted effects. Bellion's scientific and commercial goals focus on the development of safe additives that provide protective effects, education of consumers concerning the documented ill effects of alcohol consumption, along with the advantages of functional beverages or spirits that aid consumers in making smarter, safer, and healthier choices. Bellion's objectives include the distribution of products and technologies that help to educate consumers about the chemical interactions of alcohol in the body (both positive and negative). To that end, Bellion Spirits petitioned TTB for permission to make health-related statements regarding NTX®, including on its labels for Bellion brand Vodka. TTB denied the Petition, and TTB's denial is the subject of this Complaint. Thus, Bellion Spirits is a person adversely aggrieved by agency action.

15. ***Chigurupati Technologies Private Ltd.*** Chigurupati Technologies Private Ltd. ("Chigurupati Technologies") is solely a Research & Development institution founded with the objective to "aid in the evolution of mankind." By focusing on research and development, Chigurupati Technologies develops and leverages innovations that later provide beneficial health products for consumers globally, thus encouraging consumer evolution. Chigurupati

[2] The labels' TTB ID numbers are 15091001000076 and 16109001000457.

Technologies depends on its ability to convey scientific literature and facts to consumers and businesses in association with its technologies. Chigurupati Technologies developed and owns a proprietary blend of three generally recognized as safe ingredients combined through a proprietary process and sold under the name "NTX®." Those three ingredients are glycyrrhizin acid, d-mannitol, and potassium sorbate. NTX® is thus an ingredient in Bellion Vodka that Bellion Spirits purchases from Chigurupati Technologies. Along with Bellion Spirits, Chigurupati Technologies petitioned TTB for permission to make health-related statements regarding NTX®. TTB denied the Petition. Thus, Chigurupati Technologies is also a person adversely aggrieved by the agency action.

16. ***Steven Mnuchin, Secretary, United States Department of the Treasury; the Unites States Department of the Treasury; John Manfreda, Administrator, Alcohol and Tobacco Tax and Trade Bureau; the Alcohol and Tobacco Tax and Trade Bureau ("TTB"); and the United States of America.*** Steven Mnuchin (sued in his official capacity) is the Secretary of the United States Department of the Treasury, the executive department having jurisdiction over the TTB. John Manfreda (sued in his official capacity) is the Administrator of the TTB. The TTB is the administrative agency granted exclusive authority by Congress to regulate distilled spirit products, which includes authority to regulate labeling and advertising of distilled spirits. The Treasury Department and the TTB are part of the executive branch of the United States government.

PROCEDURAL HISTORY

17. The Federal Alcohol Administration Act ("FAA Act" or "FAAA") exclusively authorizes TTB to issue regulations concerning the packaging, labeling and advertising of alcohol beverages to: (1) prohibit consumer deception and (2) prohibit, irrespective of falsity,

statements relating to analyses, guarantees, and scientific or irrelevant matters that are likely to mislead the consumer. *See* 27 U.S.C. § 205(e)-(f). Although the FAA Act generally requires bottlers and importers of alcohol beverages to obtain certificates of label approval ("COLA") prior to the bottling or importation of alcohol beverages for sale in interstate commerce, it does not require pre-approval of advertising.

18. In 2003, TTB issued a final rule on specific health claims and other health-related statements in the labeling and advertising of alcohol beverages, including distilled spirits. *See* 68 Fed. Reg. 10076 (Mar. 3 2003) (Health Claims and Other Health-Related Statements in the Labeling and Advertising of Alcohol Beverages).

19. Under the final rule, labels and advertisements may not contain any health-related statement,[3] including a specific health claim,[4] that is untrue in any particular or that tends to

[3] As used in the TTB's regulations, the term "health-related statement" means:

> [A]ny statement related to health . . . and includes statements of a curative or therapeutic nature that, expressly or by implication, suggest a relationship between the consumption of alcohol, distilled spirits, or any substance found within the distilled spirits, and health benefits or effects on health. The term includes both specific health claims and general references to alleged health benefits or effects on health associated with the consumption of alcohol, distilled spirits, or any substance found within the distilled spirits, as well as health-related directional statements. The term also includes statements and claims that imply that a physical or psychological sensation results from consuming the distilled spirits, as well as statements and claims of nutritional value (*e.g.*, statements of vitamin content). Statements concerning caloric, carbohydrate, protein, and fat content do not constitute nutritional claims about the product.

27 C.F.R. §§ 5.42(8)(i)(A), 5.65(d)(1)(i).

[4] As used in the TTB's regulations, the term "specific health claim" means:

> [A] type of health-related statement that, expressly or by implication, characterizes the relationship of the distilled spirits, alcohol, or any substance found within the distilled spirits, to a disease or health-related condition. Implied specific health claims include statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a

create a misleading impression as to the effects on health of alcohol consumption. *See* 27 C.F.R. § 5.42(b)(8)(ii) (labels); *id*. at § 5.65(d)(2) (advertisements).

20. Under its rules, TTB will not approve any health-related statement that is a specific health claim unless it: (1) is truthful and adequately substantiated by scientific or medical evidence; (2) is sufficiently detailed and qualified with respect to the categories of individuals to whom the claim applies; (3) adequately discloses the health risks associated with both moderate and heavier levels of alcohol consumption; and (4) outlines the categories of individuals for whom any alcohol consumption poses risks. *Id*. at §§ 5.42(b)(8)(ii)(B)(2), 5.65(d)(2)(ii).

21. If the health-related statement conveys a misleading impression, TTB may require a prominent disclaimer or other qualifying statement for the purpose of dispelling the misleading impression. *See, e.g*., *id*. at § 5.42(b)(8)(ii)(A).

22. Unlike the Federal Food and Drug Administration ("FDA"), TTB has yet to adopt workable regulatory procedures and criteria for the evaluation of health-related statements, contributing to blanket suppression of truthful health claims on the label, in the labeling, and in the advertising of alcohol.

23. On April 12, 2016, Plaintiffs petitioned TTB for permission to use health-related statements for NTX® containing alcoholic beverages. Specifically, Plaintiffs' Petition requested that TTB "declare, via rulemaking or through the exercise of enforcement discretion, that the use of the [Plaintiffs'] proposed health-related statements concerning the hepatoprotective and DNA-

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> relationship exists between distilled spirits, alcohol, or any substance found within the distilled spirits, and a disease or health-related condition.

27 C.F.R. §§ 5.42(8)(i)(B), 5.65(d)(1)(ii).

protective effects of NTX® in the labeling and advertising of wine, distilled spirits, and malt beverages is permissible."

24. The "proposed-health related statements" that were the subject of the Petition included eight claims (only two of which, the last two here listed, are the subjects of the instant challenge):

- NTX® provides antioxidant and anti-inflammatory support (hereinafter "Claim I")
- NTX® helps protect against, i.e., reduces, alcohol-induced oxidative damage to the liver (hereinafter "Claim II");
- NTX® helps maintain normal liver enzyme production and function (hereinafter "Claim III");
- NTX® supports normal liver defenses and regenerative mechanisms (hereinafter "Claim IV");
- NTX® reduces the risk of alcohol-induced liver diseases, including fibrosis and cirrhosis (hereinafter "Claim V");
- NTX® helps maintain normal liver functions (hereinafter "Claim VI");
- NTX® helps protect DNA from alcohol-induced damage (hereinafter "Claim VII"); and
- NTX® reduces alcohol-induced DNA damage (hereinafter "Claim VIII").

25. Only Claims VII and VIII, which concern reduction in alcohol-induced DNA damage, are at issue in this Complaint ("NTX® helps protect DNA from alcohol-induced damage" and "NTX® reduces alcohol-induced DNA damage").

26. Plaintiffs were willing to accept any reasonable disclaimer designed to eliminate any unintended potential for misleadingness arising from the above claims, including the following which they proposed as a non-exhaustive example to TTB:

> NTX® does not protect against all health risks associated with moderate and heavy levels of alcohol consumption, including, but not limited to, motor vehicle accidents, high blood pressure, stroke, cancer, birth defects, psychological

> problems, and alcohol dependency. Do not consume alcohol if: you are younger than the legal drinking age; you are pregnant or may become pregnant; you are taking medicine that can interact with alcohol; you have a medical condition for which alcohol is contraindicated; you plan to drive; or you cannot restrict your drinking to moderate levels. If you consume alcohol, only consume it in moderation. "Moderation" means up to one drink per day for women and up to two drinks per day for men.

27. In a letter dated May 26, 2016, TTB acknowledged receipt of the Petition. TTB interpreted the Petition as a request that TTB issue a ruling on whether use of the eight health-related statements would violate TTB regulations, or, in the alternative, that TTB initiate rulemaking to allow the use of the eight health-related statements on labels and in advertisements. Thus, TTB assigned the Petition to its Regulations and Rulings Division for review.

28. The May 26, 2016 letter also informed Plaintiffs that TTB forwarded the Petition, including its exhibits, to FDA, so that TTB could consult with FDA officials as set forth in 27 C.F.R. §§ 5.42(b)(8)(ii)(B)(1), 4.39(h)(2)(ii)(A) and 7.29(e)(2)(ii)(A), which provide that TTB will consult with FDA, as needed, on the use of a specific health claim on labels, and that TTB will not approve the use of a specific health claim if FDA determines that the labeling claim is a drug claim that violates the federal Food, Drug, and Cosmetic Act ("FDCA").

29. Plaintiffs had previously objected to FDA review, explaining that FDA lacks the statutory authority to interpret the FAA Act and the TTB's regulations for the regulation of alcoholic beverage claims.

30. In a letter dated July 12, 2016, TTB told Plaintiffs that it was actively reviewing the Petition, including its exhibits, and would provide the Plaintiffs with an update by October 10, 2016.

31. In a letter dated October 7, 2016, TTB said that it was "still reviewing the health-related statements at issue to determine if they comply with TTB regulations," and would issue a decision on the Plaintiffs' petition by November 10, 2016.

32. On November 1, 2016, Plaintiffs submitted a "Supplement" to their Petition. The Supplement included five additional exhibits, which the Plaintiffs referred to as constituting "additional and compelling evidence, including a peer-reviewed article and two new human clinical studies, confirming the hepatoprotective and DNA protective effects of NTX®." The cover letter to the Supplement stated that the Plaintiffs expected TTB's "decision to encompass the supplemental exhibits. . ."

33. In a letter dated November 10, 2016, TTB said that it was consulting with FDA about the five additional exhibits submitted with the Supplement, and that it would provide another update to the Plaintiffs by December 9, 2016.

34. In a letter dated December 9, 2016, TTB told Plaintiffs that it anticipated it could provide a decision within 90 days from the date of the letter, and that its response would include its review of the materials submitted with the Petition and the Supplement.

35. In a letter dated March 20, 2017, TTB said it was finalizing its review of the Petition, including the Supplement and all exhibits, and anticipated that it would provide a decision on the Petition by April 7, 2017.

36. In a letter dated May 3, 2017 (hereinafter referred to as "Denial Letter"), TTB explained to Plaintiffs that it was denying their request to initiate rulemaking on the eight proposed health-related statements, or to initiate a ruling that would authorize the use of such statements on labels or in advertisements.

THE BELLION HEALTH CLAIM PETITION AND SUPPLEMENT

37. Plaintiffs petitioned TTB for permission to use eight health-related statements concerning NTX®. Only Claims VII and VIII, which concerned the ability of NTX® to protect DNA from alcohol-induced damage ("NTX® helps protect DNA from alcohol-induced damage" and "NTX® reduces alcohol-induced DNA damage"), are at issue in this Complaint.

38. In their Petition, Plaintiffs documented the bases for concluding that Claims VII and VIII were truthful and adequately substantiated by credible scientific and medical evidence which they provided to TTB, noting that the wealth of peer-reviewed literature, animal studies, human clinical test data, and product-specific testing, show that NTX® and its major components reduce DNA damage from DNA single and double strand breaks induced by alcohol and other ROS generating systems in the liver.

39. Plaintiffs provided the following expert reports to TTB: (1) Stohs – Research Supporting the Health Claims for NTX, a Product Composed of Glycyrrhizin and Mannitol, in Conjunction with Alcohol Consumption; (2) Preuss – Commentary on the Report of Dr. Sidney J. Stohs Concerning the Health Clams for NTX, a Product Composed of Glycyrrhizin and Mannitol, in Conjunction with Alcohol Consumption; and (3) Stohs – White Paper: NTX® - DNA and Tissue Protective Effects in Association with Alcohol Consumption.

40. The experts concluded that the scientific evidence Plaintiffs provided to TTB, including animal, *in vitro*, and human studies, was credible and adequately substantiated Claims VII and VIII.

41. Examples of credible original scientific evidence that substantiated Claims VII and VIII include, but are not limited to, the following human studies evaluating NTX® containing Bellion Vodka: (1) Pandit – Study on the Evaluation of Hepatoprotective and Anti-

Oxidant Effect of Processed Glycyrrhiza glabra fortified Ethanol (NTX) in Alcoholic Subjects (referred to as the "first Pandit study," and submitted with the Petition); (2) Pandit – Study on the Evaluation of Hepatoprotective and Anti-Oxidant Effect of Processed Glycyrrhiza glabra fortified Ethanol (NTX) in Alcoholic Subjects (referred to as the "second Pandit study," and submitted with the Supplement);[5] and (3) Nobel – NTX Protective Effects from Alcohol Induced ROS and Genotoxicity.

42. Regarding the first Pandit study in particular, which was a randomized, double-blind, placebo-controlled crossover study, both experts Stohs and Preuss found it to be credible scientific evidence in support of Claims VII and VIII. In the study, 31 subjects received alcohol with and without NTX®, with a seven day crossover-washout provided between treatments. Three state-of-the-art assays were performed to assess the alcohol-induced DNA damage: the

[5] Two of the Pandit studies had the same title, but were different studies. To differentiate them, TTB referred to them as the "first Pandit study" and the "Pandit study."

single cell electrophoresis comet assay, [6] the cytokinesis-block micronucleus assay, [7] and the 8-hydroxy-2-deoxyguanosine formation assay. [8] The three assays each established that Bellion Vodka with NTX® significantly reduced the levels of DNA damage caused by alcohol.

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[6] In an independent review of the scientific research supportive of Claims VII and VIII, Dr. Jeffrey Blumberg, Ph.D., FASN, FACN, CNS, Associated Director and Senior Scientist at the Antioxidant Research Laboratory of the Jean Mayer USDA Human Nutrition Research Center at Tufts University, describes as follows the state-of-the-art comet assay used in the original research evaluating NTX®:

> One such approach to measuring DNA damage to one or both chromosome strands (chromatids) is the comet assay which uses single-cell gel electrophoresis to measure DNA strand breaks (Azqueta and Collins 2013). The comet assay is so named because the structure image analysis of the cell resembles a comet with a head and tail. The circular head corresponds to the undamaged DNA that remains in the body of the nuclear core ("head") and the brighter and longer the tail, the higher the level of DNA damage. The comet assay is very sensitive and can quantify the presence of a wide variety of DNA lesions, particularly single and double strand breaks. In the comet assay, the tail length (the distance of DNA migration from the head) is used to evaluate the extent of DNA damage. The Olive tail moment (the product of the tail length and the fraction of total DNA in the tail) incorporates a measure of both the smallest detectable size of migrating DNA (tail length) and the number of broken pieces of DNA (image intensity).

[7] According to Dr. Blumberg:

> The CBMN assay is a comprehensive system for measuring DNA damage including chromosome breakage, DNA misrepair, chromosome loss, non-disjunction, necrosis, apoptosis and cytostasis (Fenech 2007). DNA damage events are scored specifically in once-divided binucleated cells and include: micronuclei (a biomarker of chromosome breakage and/or whole chromosome loss), nucleoplasmic bridges (a biomarker of DNA misrepair and/or telomere end-fusions), and nuclear buds (a biomarker of elimination of amplified DNA and/or DNA repair complexes). Cytostatic effects are measured via the proportion of mono-, bi- and multinucleated cells and cytotoxicity via necrotic and/or apoptotic cell ratios. Centromere and/or telomere probes can be utilized to independently determine each of these three biomarkers. The CBMN assay has been broadly applied to biomonitoring in vivo genotoxin exposure, in vitro genotoxicity testing, nutrigenomics and pharmacogenomics studies as well as tumor radiation sensitivity and cancer risk.

[8] Dr. Blumberg explained this assay as follows:

43. In his White Paper, Dr. Stohs concluded that a second randomized, double-blind, placebo crossover study also substantiated Claims VII and VIII. The study was entitled, "Antioxidant and DNA Protective Effects of NTX, a Proprietary Glycyrrhizin/D-Mannitol Product, in Association with Alcohol Consumption: A Randomized Placebo-Controlled Double-Blinded Crossover Study." It was similar in design to the first Pandit study, but involved 50 subjects. It used the same three assays as the Pandit study to measure DNA damage. All three assays again demonstrated that Bellion Vodka with NTX® protected against alcohol-induced DNA damage.

44. Dr. Stohs further found that a third human crossover, double-blinded, randomized two group study substantiated Claims VII and VIII. In that study, 13 male and 12 female subjects consumed alcohol with and without NTX®. That study relied on the comet assay to document DNA damage. It found that consumption of Bellion Vodka with NTX® decreased the extent of DNA damage by 83% as compared to the consumption of alcohol alone.

45. Examples of animal and *in vitro* studies the experts found to be credible scientific evidence also substantiated Claims VII and VIII include but are not limited to: a rat study that found glycyrrhizin and d-mannitol synergistically worked together to protect DNA from alcohol

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> Oxidative and nitrosative attack on DNA can lead to adducts that impair base pairing and/or block DNA replication and transcription, base loss, or DNA single-strand breaks. In assessing the steady-state level of DNA damage, i.e., the balance between formation and repair, the most frequent oxidative adult is typically 8-OHdG, occurring at an average frequency of 2400 per cell. The formation of 8-OHdG can increase up to ten-fold in the presence of a potent oxidizing stress. While 8-OHdG is the most commonly tested adduct, other lesions, such as formamido pyrimidine, 2,6-diamino-4-hydroxy-5-formamidopyrimidine, and 4,6-diamino-5-formamido pyrimidine are also formed at rates close to 8-OHdG after oxidative stress. Nonetheless, 8-OHdG is most commonly employed as a biomarker of DNA damage, oxidative stress, and carcinogenesis as it has been linked directly to modulation of gene expression and the induction of mutations.

damage; a human tissue study that found glycyrrhizin significantly reduced DNA damage in human epithelial cells as evidenced by a single gel electrophoresis assay; and a study that found mannitol prevented DNA damage in the *in vitro* systems involved in normal human keratinocytes.

TTB DENIAL LETTER

46. In its Denial Letter, TTB, after consultation with FDA, imposed a blanket ban on Plaintiffs' use of all claims sought, including Claims VII and VIII that are the subject of this Complaint, in violation of Plaintiff's First Amendment rights. Specifically, TTB denied the Plaintiffs' "request to initiate rulemaking on the claims, or to issues a ruling that would authorize the use of such statements on labels or in advertisements."

47. In denying Plaintiffs' Petition, TTB admitted that under its rules the proposed health-related statements did constitute explicit or implicit specific health claims, regulable by TTB.

48. As health-related statements that were also specific health claims, TTB asserted that they were subject to the following three regulations: (1) 27 C.F.R. § 5.42(a)(1), which prohibits statements that are "false or untrue in any particular, or that, irrespective of falsity, directly, or by ambiguity, omission, or inference, or by the addition of irrelevant, scientific or technical matter, tend[] to create a misleading impression"; (2) 27 C.F.R. § 5.42(b)(8)(ii)(A), which provides that a health-related statement must not be "untrue in any particular or tend[] to create a misleading impression as to the effects on health of alcohol consumption"; and (3) 27 C.F.R. § 5.42(b)(8)(ii)(B)(2), which states that any health-related statement that is also a "specific health claim" must, *inter alia*, be "truthful and adequately substantiated by scientific or medical evidence."

49. TTB's Denial Letter was limited to assessment of whether the proposed claims were truthful and adequately supported by credible scientific or medical evidence in satisfaction of the third above-referenced requirement for adequate substantiation.

50. Rather than make the credible science determination itself under TTB standards, TTB referred the review to FDA under FDA standards.

51. TTB asserted that FDA had expertise in assessing the kinds of articles and studies the Petition and Supplement relied upon, and such expertise would aid TTB in its assessment of the proposed specific health claims. Thus, on April 26, 2016, TTB sent the Petition, including its exhibits, to FDA. TTB did not specify any criteria from its own rules to guide FDA in assessing the scientific evidence, leaving it instead to FDA to rely on FDA's own statutory and regulatory standards.

52. Originally, TTB asked FDA to: (1) determine if any of the proposed claims were drug claims that would violate the federal Food, Drug, and Cosmetic Act; and (2) analyze the scientific data submitted in the exhibits that and offered in support of the proposed claims.

53. Upon further reflection, TTB determined that the Petition presented the threshold question of whether the proposed health-related statements were truthful and adequately substantiated by scientific or medical evidence, and if that threshold question was answered in the negative, it would then be unnecessary for FDA to determine whether the claims would violate the FDCA. As a result, TTB subsequently limited the scope of its consultation with FDA but again failed to define a standard of review for FDA to use, relying instead on FDA to review the science under FDA's own statutory and regulatory standards. Specifically, TTB requested that FDA consult only on the scientific and medical evidence. For example, when TTB received Plaintiffs' November 1, 2016 Supplement to the Petition, it later sent a letter to the FDA with a

copy of the Supplement that asked for "FDA's views on whether the scientific data submitted in the petition, including the exhibits in the Petition Supplement, adequately substantiate the proposed claims set for the in the petition." TTB also explained in its letter that FDA was not to consult on the drug claim issue, and that TTB would "let FDA know if TTB determines that it is appropriate to request such a consultation after FDA has provided a consultation on whether the petition, as supplemented by the newly submitted exhibits, substantiates the proposed health-related statements."

54. At TTB's request, FDA evaluated 112 articles and studies Plaintiffs submitted with the Petition and Supplement in support of all eight of their health-related statements.

55. FDA dismissed outright, without substantive evaluation, 106 studies, irrespective of which health-related statement they supported, on the ground that scientific conclusions could not be drawn from them for one or more of the following reasons:

- the studies did not evaluate NTX® *per se*, but rather individual components of NTX® (glycyrrhizin or mannitol);
- the studies were conducted in animals or *in vitro*;
- the articles were not on the findings of studies, but rather book chapters, review articles, government and WHO documents, or patents;
- the studies were published in a foreign language;
- the studies were conducted in individuals who already had liver disease (e.g., hepatitis);
- the study measured endpoints other than those that are the subject of the proposed claims (e.g., pancreatitis, renal failure); and/or
- the studies did not evaluate NTX® or individual components of NTX®.

56. TTB adopted FDA's position and FDA's statutory and regulatory criteria for claims review, FDA's dietary supplement and drug standards, doing so without equivocation, and rejected the very same 106 articles and studies that FDA rejected. For example, in the Denial Letter, TTB stated, "[I]n reliance on FDA's criteria – including its position on animal and in vitro studies – TTB determined that 106 of the articles and studies submitted by the petitioners do not allow scientific conclusions to be drawn about the claims. Because TTB is relying on FDA's criteria, those articles cannot provide the basis for finding that the petition's specific health claims are adequately substantiated by scientific or medical evidence."

57. FDA and TTB rejected an additional study, referred to as the first Pandit study in TTB's Denial Letter, because it did not report certain information, e.g., information about study subjects, study design, dose of NTX® provided, and the appropriateness of the control group.

58. Of the remaining five studies, two of them were on findings of the same study, with one being a published version of the other. Thus, FDA determined to give only four separate studies out of the original 112 studies detailed consideration.

59. Those four studies are as follows: (1) Chigurupati – Evaluation of Reactive Oxygen Species (ROS); (2) Udani – Hepatoprotective Effects of a Proprietary Product during Alcohol Consumption; (3) Pandit – Study on the Evaluation of Hepatoprotective and Antioxidant Effect of Processed Glycyrrhiza glabra Fortified Ethanol (NTX) in Alcoholics Subjects ("the Pandit Study" submitted with the Supplement); and (4) Nobel – NTX Protective Effects from Alcohol Induced ROS and Genotoxicity.

60. FDA then assessed whether the four studies, individually or collectively, substantiated Plaintiffs' proposed health-related statements, including Claims VII and VIII. *Id.* at 32-42. When assessing the studies, FDA used criteria set forth in, *inter alia*, its *Guidance for*

Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims – Final Guidance, January 2009, which applies to foods, including dietary supplements.

61. FDA criticized the remaining four studies generally on the grounds that: (1) the studies allegedly lacked information about the dosage of NTX® consumed by the study subjects; and (2) the studies allegedly measured biomarkers that were not valid surrogates for long-term risk of liver disease.

62. Regarding Claim VII in particular ("NTX® helps protect DNA from alcohol-induced DNA") damage, FDA stated:

> The evidence was mixed for NTX in protecting DNA from alcohol-induced damage, with one study (Pandit), representing 50 subjects, showing a significant reduction in certain measures of DNA damage at some but not all time points after administration of NTX, and a second study (Nobel), representing 25 subjects, showing no effect on protecting DNA.
>
> Many of the same limitations apply as are discussed above regarding the evidence for antioxidant support and anti-inflammatory support - specifically, the studies do not provide information on the amount of NTX consumed, and the studies do not purport to assess long-term effects. Based on these studies, the short-term ability of NTX to protect DNA from alcohol-induced damage is not clear. As described above, one study showed no effect, while a second study showed an effect at some but not all time points.

63. Concerning Claim VIII ("NTX reduces alcohol-induced DNA damage"), FDA similarly stated:

> The evidence was mixed for NTX in reducing alcohol-induced DNA damage, with one study (Pandit), representing 50 subjects, showing a significant reduction in certain measures of DNA damage at some but not all time points after administration of NTX, and a second study (Nobel), representing 25 subjects, showing no effect on protecting DNA.
>
> Many of the same limitations apply as are discussed above regarding the evidence for antioxidant support and anti-inflammatory support - specifically, the studies do not provide information on the amount of NTX consumed, and the studies do not purport to assess long-term effects. Based on these studies, the short-term ability of NTX to reduce alcohol-induced damage is not clear. As described

above, one study showed no effect, while a second study showed an effect at some but not all time points.

64. TTB relied upon and adopted FDA's findings without equivocation. For example, TTB adopted FDA's criticism that the lack of dosage information made it impossible to draw any valid scientific conclusions regarding whether studies' results are applicable to the levels of NTX® in commercially available alcoholic beverages. TTB also adopted FDA's criticism that the studies did not purport to assess long-terms effects of NTX.

65. Although the two DNA claims made no mention of alcohol induced liver and brain damage, TTB interpreted Claims VII and VIII as implying that "consuming an alcohol beverage infused with NTX® will provide a reduction of risk from alcohol-induced damage to DNA, and thus protect from alcohol-induced damage to the liver and the brain." Because "U.S. Government publications indicate that alcohol-induced liver damage generally results from long-term, heavy consumption of alcohol," TTB said that Claims VII and VII implied that "NTX® will have the long-term effect of protecting DNA from alcohol-induced damage and reducing alcohol-induced DNA damage in a way that meaningfully protects consumers from alcohol-induced liver and brain damage."

66. According to TTB, the studies provided no credible evidence for the implied meaning of Claims VII and VIII because the studies did not address the long-term hepatoprotective effects or measure risk biomarkers that are considered surrogate endpoints of liver disease. Thus, TTB concluded that Claims VII and VIII were not adequately substantiated by Plaintiffs' evidence.

67. To compare, TTB indicated that the evidence was "mixed" for a differently worded claim regarding short-term DNA protection, noting that FDA found that one study showed no effect in protecting DNA, while another study showed a "significant reduction in

certain measures of DNA damage at some point but not all time points after administration of NTX."

68. TTB further alleged that Claims VII and VIII tended to create a misleading impression as to the effects of alcohol consumption on health in violation of 27 C.F.R. § 5.42(b)(8)(ii)(A), which provides that "labels may not contain any health-related statement that is untrue in any particular or tends to create a misleading impression as to the effects on health of alcohol consumption." TTB based this allegation on its interpretation that the Claims "convey the message that consumption of alcohol beverages infused with NTX® will somehow reduce the long-term health risks otherwise associated with both moderate and heavy levels of alcohol consumption, specifically liver disease and brain damage," but, while the existence of the health risks is well established, the protective effects of NTX® are not adequately established. TTB said that "[i]t is clearly misleading to explicitly or implicitly claim that an alcohol beverage infused with NTX® will reduce the serious long-term health risks posed by alcohol consumption and abuse without credible evidence."

69. Finally, TTB claimed that the Petitioners' proposed disclaimer "does not cure the misleading nature of the proposed claims or adequately address the requirements for qualifying language that must be present for specific health claims." TTB also *sub silencio* "considered but rejected use of a different disclaimer to accompany the proposed claims."

CLAIMS FOR RELIEF
COUNT 1

TTB'S BLANKET BAN ON CLAIMS VII AND VIII VIOLATES THE FIRST AMENDMENT TO THE UNITED STATES CONSTITUTION

70. Plaintiffs incorporate by reference all allegations contained in paragraph 1 through 69, *supra*.

71. Plaintiffs' Claims VII and VIII, which TTB sub-categorized as specific health claims, convey information essential for the exercise of informed consumer choice in the market and is protected from government censorship under the First Amendment to the U.S. Constitution. *See Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980) and progeny.

72. TTB's Denial Letter violates the First Amendment because it prohibits the use of Claims VII and VIII despite the fact that they are substantiated by credible scientific evidence and are non-misleading. Experts Drs. Stohs and Preuss, as well as Dr. Jeffrey B. Blumberg, Ph.D., FASN, FACN, CNS, Associate Director and Senior Scientist at the Antioxidant Research Laboratory, Jean Mayer USDA Human Nutrition Research Center, Tufts University, in his complementary report entitled, "Report on Health Claims that NTX® Helps Protect DNA from Alcohol-induced Damage and Reduces Alcohol-induced DNA damage," have found that human, animal, and *in vitro* studies demonstrate that NTX® helps protect DNA from alcohol-induced damage.

73. Plaintiffs submitted 112 studies supporting their Petition. In reliance upon FDA's dietary supplement and drug standards and evaluation thereunder, TTB dismissed 106 of those studies, irrespective of the Claim they applied to, because, it determined that scientific conclusions could not be drawn. The TTB erred in rejecting outright more than 100 supportive scientific studies without examining their scientific content in detail in accordance with generally accepted scientific principles. Thus, TTB created an intentionally biased and truncated scientific record inconsistent with the totality of relevant evidence.

74. In the Denial Letter, TTB cited to *POM Wonderful, LLC v. FTC*, 777 F.3d 478, 505 (D.C. Cir. 2015), *cert. denied*, 136 S. Ct. 1839 (2016), doing so incorrectly for the

proposition that TTB has the power to reject any kind of evidence, in its discretion, if it deems there to be an insufficient "relationship between a substance and a disease in humans." However, that citation fundamentally misrepresents *POM Wonderful*, where the claims made by the company were deemed deceptive under the Federal Trade Commission Act on the basis that studies contradicted the science offered in support of the claim. Moreover, the case was inapposite because FTC does not engage in prior restraint of speech, as TTB imposes here, but in post publication review under deceptive advertising standards, which differ fundamentally form FDA and TTB standards for pre-publication review.

75. TTB also ignored the teachings of *Central Hudson* and its progeny, in failing to discuss or otherwise state the grounds for why its means, a total speech ban, were "no more extensive than necessary to serve [the interest of ensuring that alcohol beverage consumers are not misled about the significant health risks associated with alcohol consumption and abuse]." Moreover, under TTB's own regulations in 27 C.F.R. § 5.42(b)(8)(ii)(A), TTB "may require as part of the health-related statement a disclaimer or some other qualifying statement to dispel any misleading impression conveyed by the health-related statement." Under that regulation, and the fourth prong of the *Central Hudson* test, TTB was required to consider whether *any* disclaimer could "dispel any misleading impression conveyed," rather than summarily determine that the label and claims were "misleading" without more.

76. By failing to consider the use of a reasonable and succinct disclaimer as a remedy for any potential misleadingness, TTB failed to comply with the constitutional requirement that the regulation on commercial speech be narrowly tailored to serve the government's interest. *See, e.g., In re R. M. J.*, 455 U.S. 191, 203, 102 S. Ct. 929, 937, 71 L. Ed. 2d 64 (1982) (the government may not place an absolute prohibition on certain types of potentially misleading

information if information may be presented in way that is not deceptive, e.g., with disclaimers or explanation, and any restriction upon such advertising must not be broader than is reasonably necessary to prevent the deception); (*Ibanez v. Florida Dep't of Bus. & Prof'l Regulation, Bd. of Accountancy*, 512 U.S. 136, 148, 114 S. Ct. 2084, 2091, 129 L. Ed. 2d 118 (1994) ("Commercial speech that is not false, deceptive, or misleading can be restricted, but only if the State shows that the restriction directly and materially advances a substantial state interest in a manner no more extensive than necessary to serve that interest."); *Bates v. State Bar of Arizona*, 433 U.S. 350, 97 S. Ct. 2691, 53 L.Ed.2d 810 (1977) (holding that "incomplete" attorney advertising was not inherently misleading and that "the preferred remedy is more disclosure, rather than less"); *Pearson v. Shalala*, 164 F.3d 650, 658 (D.C. Cir. 1999) (noting that under the commercial speech doctrine, there is a "preference for disclosure over outright suppression" and for "less restrictive and more precise means" of regulating commercial speech) (internal quotation marks omitted). In fact, TTB implied that a disclaimer regarding the strength of evidence in support would be sufficient as a disclaimer.

77. A blanket ban on the claims, as the TTB imposes here, requires "empirical evidence in connection with the government's outright ban on the proposed health claim." *See Fleminger, Inc. v. U.S. Dep't of Health and Human Servs.*, 854 F. Supp. 2d 192, 216 (D. Conn. 2012). Further, a complete ban of a proposed health-related statement may only occur when there is little to no qualitative evidence in support of the claim and where the government has demonstrated with empirical evidence that the public would be deceived even with the use of a disclaimer. *See Whitaker v. Thompson*, 248 F. Supp. 2d 1, 11 (D.D.C. 2002) (citing *Pearson v. Shalala*, 164 F.3d 650, 659–60 (D.C. Cir. 1999). No such empirical evidence concerning the proposed health statements exists. Moreover, where there is no credible scientific evidence

against a claim, as here, the presence of credible scientific evidence in support of it requires that the claim be allowed into the market. *See, e.g., All. for Nat. Health U.S. v. Sebelius*, 714 F. Supp. 2d 48 (D.D.C. 2010).

78. This Court exercises *de novo* review of constitutional challenges to agency actions. The Court must make an independent assessment of the constitutional claim and need not accord deference to the agency's decision. The Court may take or receive evidence in conducting *de novo* review.

COUNT 2

TTB VIOLATED THE FAA ACT BY DEFERRING TO FDA FOR AN ULTIMATE EVALUATION OF THE EVIDENCE IN SUPPORT OF CLAIMS VII AND VIII UNDER FDA'S INAPPOSITE STANDARDS

79. Plaintiffs incorporate by reference all allegations contained in paragraph 1 through 78, *supra*.

80. Without express congressional authority (or authority in the Executive Branch of government to apportion administrative duties), an agency may not act beyond the limits of its enabling statute.

81. An administrative agency, like TTB, may not act without specific Congressional authorization. *See, e.g., Transohio Sav. Bank v. Dir., Office of Thrift Supervision*, 967 F.2d 598, 621 (D.C. Cir. 1992) ("It is central to the real meaning of 'the rule of law,' [and] not particularly controversial that a federal agency does not have the power to act unless Congress, by statute, has empowered it to do so."); *La. Pub. Serv. Commn. v. FCC*, 476 U.S. 355, 374 (1986) ("[A]n agency literally has no power to act . . . unless and until Congress confers power upon it."); *Adams Fruit Co., Inc. v. Barrett*, 494 U.S. 638, 650 (1990) (stating that "[a]lthough agency determinations within the scope of delegated authority are entitled to deference, it is fundamental

'that an agency may not bootstrap itself into an area in which it has no jurisdiction'") (quoting *Fed. Mar. Commn. v. Seatrain Lines, Inc*., 411 U.S. 726, 745 (1973)); *Am. Library Assn. v. FCC*, 406 F. 3d 689, 702 (D.C. Cir. 2005) (an agency does not possess plenary authority to act within a given area simply because Congress has endowed it with some authority to act in that area); *In re Keim*, 212 B.R. 493, 499 (Bkrtcy. D. Md. 1997) ("An act of a governmental agency is *ultra vires* if it is beyond the express or implied powers conferred by statute."). Accordingly, "[a]gency action taken without statutory authorization, or which frustrates the congressional policy which underlies a statute, is invalid." *Yankton Sioux Tribe v. Kempthorne*, 442 F. Supp. 2d 774, 784 (D.S.D. 2006).

82. Here, Congress delegated exclusive regulatory authority over spirit products to the Bureau of Alcohol, Tobacco, Firearms and Explosives ("ATF"), which authority includes regulation of alcohol labeling and advertising. *See* 27 U.S.C. §§ 201, *et seq*. ATF then delegated its authority to approve certificates of label approval ("COLAs") to TTB. *See Reorganization of Title 27, Code of Federal Regulations*, 68 Fed. Reg. 374401 (Jan. 2003).

83. FDA, by contrast, lacks statutory authority to regulate alcoholic spirits within the TTB's exclusive purview. In 1974, ATF and FDA entered into a Memorandum of Understanding stating that "BATF in consultation with FDA was developing comprehensive ingredient labeling regulations with respect to distilled spirits, wine and malt beverages …" *Brown-Forman Distillers Corp. v. Mathews*, 435 F. Supp. 5, 8 (W.D. Ky. 1976). FDA has been precluded, however, from directly regulating alcoholic beverages, because, as the government admitted, "it was Congress' intention to place exclusive jurisdiction in BATF with respect to regulating the labeling of alcoholic beverages." *Id.* at 17. *See also Brown-Forman Distillers*

Corp. v. Mathews, 435 F. Supp. 5, 8 (W.D. Ky. 1976) ("it was Congress' intention to place exclusive jurisdiction in BATF with respect to regulating labeling of alcoholic beverages.").

84. Despite the clear congressional mandate, ATF enacted regulations in 27 C.F.R. § 5.42(b) that specifically authorize TTB to "consult with the Food and Drug Administration (FDA), as needed, on the use of a specific health claim on a distilled spirits label." *See* 27 CFR § 5.42(b)(8)(ii)(B)(1).

85. Under section 5.42, TTB referred the Plaintiffs' voluminous scientific and evidentiary record to FDA for FDA to assess whether the scientific data submitted in the Petition, including the exhibits in the Petition Supplement, adequately substantiated the eight proposed health-related statements. FDA subsequently determined under its standards for dietary supplement and drug claims, and not under TTB standards, that the claims for alcohol products were not adequately substantiated, and TTB adopted FDA's findings, which were based exclusively on FDA's statutory and regulatory standards for dietary supplements and drugs, without equivocation.

86. In prohibiting Claims VII and VIII on the ground that they lacked adequate substantiation, TTB relied upon FDA's inapposite criteria for health claims, particularly FDA's January 2009 *Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health claims- Final* applicable to dietary supplements and foods, and other guidances and regulations not applicable to alcohol. TTB explained in its Denial Letter that "[t]he criteria articulated in FDA's guidance and regulations are relevant in determining whether a specific health claim is 'truthful and adequately substantiated by scientific or medical evidence,' within the meaning of the applicable TTB regulations, because those criteria provide a systematic and science-based approach to assess whether the evidence in support of a specific

health claim actually substantiates it." On their face the standards do not apply to alcohol, and TTB has not adopted those standards through independent rulemaking and, thus, has not afforded the public opportunity for notice and comment as to their applicability in the alcohol context.

87. Two conclusions are apparent from TTB's actions. First, TTB expressly delegated the task of reviewing the health-related statements to FDA contrary to the FAA Act which vests that review function exclusively in TTB. Second, TTB conceded that it lacks an independent expertise to evaluate health-related statements, particularly where, under 27 CFR § 5.42(b)(8), they necessarily involve "statements of a curative or therapeutic nature." *See* 27 C.F.R. § 5.42(b)(8)(i)(A).

88. The FAAA exclusively vests in TTB the authority to review alcoholic beverage claims, and nothing in the FAAA grants TTB authority to delegate that review to FDA. FDA similarly lacks primary authority to regulate the labels, labeling, and advertising of alcohol. *See Brown-Forman Distillers*, 435 F. Supp. at 12 ("we are fully convinced that it was Congress' intention to place exclusive jurisdiction to regulate the labeling of alcoholic beverages in the BATF"). Accordingly, TTB's denial of Plaintiffs' Claims VII and VIII is the result of *ultra vires* agency action in violation of TTB's enabling statute. *See, e.g., Fed. Trade Comm'n v. Liggett & Myers Tobacco Co.*, 108 F. Supp. 573, 577 (S.D.N.Y. 1952) (prohibiting FTC from regulating cigarette advertising because, although FTC had authority under the Federal Trade Commission Act to regulate drugs, a cigarette was not a "drug" for purposes of the FTCA, and an "agency must not exceeds the bounds of its statute").

COUNT 3

DUE PROCESS: TTB'S FAILURE TO ADOPT, EXPLAIN, AND OFFER CLEAR GUIDELINES GOVERNING THE APPROVAL OF ALCOHOLIC BEVERAGE HEALTH CLAIMS DEPRIVED PLAINTIFF OF PROCEDURAL DUE PROCESS

89. Plaintiffs incorporate by reference all allegations contained in paragraph 1 through 88, *supra*.

90. "Procedural due process imposes constraints on governmental decisions which deprive individuals of 'liberty' or 'property' interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment." *Mathews v. Eldridge*, 424 U.S. 319, 332 (1976).

91. In analyzing a claim of deprivation of procedural due process, courts apply a two part test: (1) whether the plaintiff had a liberty or property interest entitled to procedural due process; and (2) if so, what process is due. *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982).

92. "Once it is determined that due process applies, the question remains what process is due." *Morrissey v. Brewer*, 455 U.S. 745, 774 (1982). "Due process means, in an elemental and fundamental sense, that there should be some form of a hearing in front of a neutral fact-finder and an opportunity to be heard 'at a meaningful time and in a meaningful manner,' before an individual is deprived of a fundamental right or property interest. *U.S. v. Karper*, 847 F. Supp. 2d 350, 357 (N.D.N.Y. 2011) (quoting *Mathews*, 424 U.S. at 333–34)). In determining what process is required, courts use a flexible standard that weighs three factors:

> [F]irst, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

Mathews, 424 U.S. at 335.

93. Here, Plaintiffs have a liberty interest in their right to disseminate truthful and non-misleading information about NTX® (a legal additive shown by credible scientific evidence to reduce the adverse effects of alcohol on DNA) on the labels, in the labeling, and in the

advertising of their alcoholic beverages that contain NTX®. *See Am. Civil Liberties of Mo. Found. v. Lombardi*, 23 F. Supp. 3d 1055, 1062 (W.D. Mo. 2014). The *American Civil Liberties* decision explained that a law deprives a party of their fundamental right to free speech either when the law has a "chilling effect" or when the law fails to provide "fair notice of what speech violates" the law. *Id.*

94. Plaintiffs suffered direct, tangible, and significant injury to their liberty interest when TTB prohibited the use of Claims VII and VIII concerning the DNA-protective effects of NTX® on labels, in the labeling, and in the advertising of Plaintiffs; NTX® containing alcoholic beverages.

95. Moreover, TTB's applicable regulations failed to provide parties, including the Plaintiffs, with fair notice of what content is prohibited. For example, TTB's health claim regulations do not articulate any standards for determining what type of scientific or medical evidence is credible. *See, e.g.,* 27 C.F.R. § 5.42(b)(8)(ii). Nor do they provide any written standards regarding the amount of credible evidence that is required to adequately substantiate a specific health claim. *See id.* As such, they are unconstitutionally vague and would allow TTB to approve or prohibit health-related statements based entirely on unarticulated and subjective criteria on a discriminatory basis. *See Quad-City Community News Service, Inc. v. Jebens*, 334 F. Supp. 8 (S.D. Iowa 1971) (finding that the vagueness or nonexistence of any written standards or regulations governing issuance of press passes violated the plaintiff's First Amendment right to freedom of the press and its Fourteenth Amendment right to procedural due process).

96. As the courts have recognized:

> It must be apparent that where public officials, in making decisions such as here involved, use (or) employ criteria or reasons that are either vague or completely unknown, the party affected has no way of knowing how to achieve compliance with the criteria nor even of challenging them as being improper. In such

> situations, the public officials literally have unimpeded discretion to regulate the activity in question in whatever manner they desire.
>
> Regulation in the area of free expression can only be tolerated when a public official's discretion is guided by narrow and specific standards which advance a compelling state interest.

Forcade v. Knight, 416 F. Supp. 1025, 1033 (D.D.C. 1976), aff'd in part, remanded in part sub nom. *Sherrill v. Knight*, 569 F.2d 124 (D.C. Cir. 1977) (quoting *Quad-City Community News Service, Inc.*, 334 F. Supp. At 17) (internal citations and quotations omitted). *See also Sherrill v. Knight*, 569 F.2d 124 (D.C. Cir. 1977) (Secret Services was required to publish or otherwise make publicly known the actual standard employed in determining whether an otherwise eligible journalist would obtain a White House press pass).

97. Plaintiffs had no way to know how to achieve compliance with TTB's unarticulated regulatory criteria for health-related statements, including specific health claims, and TTB used its unbridled discretion to prohibit claims VII and VIII in violation of the Plaintiffs procedural due process rights.

RELIEF REQUESTED

WHEREFORE, Plaintiffs respectfully request that this Court,

(1) **Declare** in accordance with the Declaratory Judgment Act, 28 U.S.C. § 2201, that TTB's Denial Letter is invalid as to Claims VII and VIII; in particular, Plaintiffs request that this Court declare:

   a. That TTB's Denial Letter violates the First Amendment to the United States Constitution in its suppression of Claims VII and VIII;

   b. That TTB's delegation of authority to FDA violates the FAA Act and the FDCA as to Claims VII and VIII; and

c. That the TTB's regulations pertaining to health-related statements are unconstitutionally vague, denying the Plaintiffs procedural due process guaranteed by the Fifth Amendment to the United States Constitution.

(2) **Order** TTB to refrain from taking any action that would preclude the Plaintiffs from using Claims VII and VIII on their labels, in labeling, or in advertising of Bellion Vodka containing NTX® and any other alcoholic beverage containing NTX®.

(3) Enjoin through a permanent injunction TTB from taking any action that would preclude the Plaintiffs from using Claims VII and VIII on their labels, in labeling, or in advertising of Bellion Vodka containing NTX® and any other alcoholic beverage that contains NTX®.

(4) Retain jurisdiction of this action to ensure compliance with this Court's decree;

(5) Grant such other and further relief as the court deems just and proper.

TRIAL BY THE COURT WITHOUT A JURY

Pursuant to 28 U.S.C. § 2402, this action shall be tried by the Court without a jury.

DATED: November 27, 2017

Respectfully submitted,
BELLION SPIRITS, LLC and
CHIGURUPATI TECHNOLOGIES PRIVATE LTD.

By _____/s/_____

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